Senior Quality Assurance Specialist

AREAS OF EXPERTISE

- **Technical operations**
- **Quality assurance**
- **Validation functions**
- **FDA consent decree**
- **Interim control**
- **Contract manufacturing**
- **Leadership for client for Quality System Element remediation steps**
- **Documentation review**
- **Batch Record Review**
- **ICH Q8 and Q9, and ASTM E2500**
- **Process technology**

INTRODUCTION

Over twenty-five years of pharmaceutical industry experience; extensive consulting experience in pharmaceutical validation functions, technical operations, and quality assurance. Dosage form experience includes direct compression solids, liquids, creams/ointments, sterile injectable, and devices.

Background and experience includes: leadership of planning and delivery of product and process transfers of solid dosage forms including experience in equipment and product and process validation planning and execution of transfers, and design of experiments (DoE) for active pharmaceutical ingredient (API).

Experience also includes documentation review of non-conformances and change controls, and project management leadership for client for Batch Record Review (BRR), and the management and the preparation of process validation and compliance audits of the documentation required following the risked-based approach (ICH Q8 and Q9, and ASTM E2500).

WORK EXPERIENCE

2010 – Present
Industry Consultant
Duties:

- Provided project leadership and facilitation to client for Corrective Action Preventative Action (CAPA) remediation in the medical device industry.
- Provided review of quality assurance documentation to Good Manufacturing Practices, Standard Operating Procedures (SOP's), and CFR 810 requirements.
- Provided project management leadership, including Gantt chart documentation to client for quality systems and Participated in client documentation review of consent decree requirements for validation and commissioning, change control, non-conformance investigations, CAPA, and BRR for manufacturing and laboratory documents.
- Reviewed process validation reports and quality systems for quality assurance audits, and generated summary reports.

2009 – 2010
Lancaster Laboratories, Inc., Lancaster, Pennsylvania
Senior Quality Assurance Specialist

- Reviewed analytical data to conform to regulatory compliance for 21 CFR Part 211.
- Authored CAPA documentation.

2007 – 2008
PharmaBio-Serv Consulting, Dorado, PR
Senior Consultant
Duties:

- Prepared documentation included validation master plans and protocols, standard operating procedures (SOP), transfer protocols, registration batch documents, CAPA, and summary reports.
- Prepared documentation for technical transfer of direct compression tablets, cream, ointment, and gel pharmaceutical processes.
- Hands-on experience included monitoring experimental and validation batches; processing and packaging.

2005 – 2007
Tunnell Consulting, King of Prussia, PA
Senior Consultant – Formulator
Duties:

- Prepared the cleaning validation master plan, test protocols and operating and analytical procedures for solids and semi-solid manufacturing facility.
- Prepared and executed design of experiment (DoE) development plans for process improvement for solid dose products to eliminate content uniformity issues with pharmaceutical active ingredient (API) in three formulations.
- Experience in development, preparation, and application of qualification and validation protocols for direct compression tablets.

1990 – 2004
Pfizer Company, Lititz, PA
Manager Process Technology Group, Contract Manufacturing, (1999 – 2004)
Duties:

- Interfaced with customers/clients to assure new product launch timetables were correct.
- Leader of teams responsible for technical transfer of pharmaceutical processes from production to contract manufacturing facilities.
- Conducted DoE for process improvements and increased manufacturing efficiencies.

Senior Process Technologist, Manufacturing Technology, (1990 – 1998)
Duties:

- Led a product development team to successfully market a dentifrice paste and gel.
- Responsible for the transfer of pharmaceutical manufacturing formulae from R&D to the production facility internal and external to the firm. Responsible for the completion of process validation on transferred formulae.
- Knowledgeable of aseptic processing.

EDUCATION

Lebanon Valley College, Annville, PA
Master of Business Administration

Shippensburg University, Shippensburg, PA
Bachelor of Science: Education in Biology/Chemistry

ASSOCIATIONS

- ISPE (International Society of Pharmaceutical Engineers)
- ASQC (American Society of Quality Control)